Notice of Allowability	Application No.	Applicant(s)	
	10/721,022	LUKAS-LASKEY ET AL.	
	Examiner	Art Unit	
	Phyllis G. Spivack	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to *Amendment and Terminal Disclaimer filed March 10, 2006*.

2. ☒ The allowed claim(s) is/are *1-30*.

3. ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
   a) ☒ All b) ☐ Some* c) ☐ None of the:
      1. ☐ Certified copies of the priority documents have been received.
      2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
      3. ☒ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

   * Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.

5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
   (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
      1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
   (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

   Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).

6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO-1449 or PTO/SB/08), Paper No./Mail Date _____
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☐ Interview Summary (PTO-413), Paper No./Mail Date _____ .
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____.

REASONS FOR ALLOWANCE

An Amendment, a Terminal Disclaimer, a Second Supplemental Reissue Declaration under 37 CFR 1.172 and 1.175 and an Information Disclosure Statement, all filed March 10, 2006, are acknowledged. Claims 1-30 remain under consideration.

Records of proceedings in four separate cases involving litigation that is unrelated to the present application and cited on the Information Disclosure Statement filed March 10, 2006 have been reviewed.

The rejection of record of claims 1-30 under the judicially created doctrine of obviousness-type double patenting, as being unpatentable over claims 1-7 of U.S. Patent 5,760,069, is withdrawn subsequent to the filing and acceptance of a Terminal Disclaimer.

The rejection of record under 35 U.S.C. 251 is withdrawn following an amendment to claims 7, 9 and 20, wherein the recitation "a risk of" is inserted. A supplemental reissue declaration is further noted. Claims 7, 9 and 20 now are in the same format as claim one.

Claims 1-30 are allowed in view of the contemporary knowledge of the cardiology art.

EXAMINER'S AMENDMENT: CLAIM 20

A method of decreasing a risk of mortality caused by congestive heart failure in a patient, said method comprising administering to said patient first dosages once or twice daily, for a period of from 7 to 28 days, said first dosages each comprising carvedilol in an amount of about 3.125 mg, then administering to said patient second dosages once

or twice daily, for a period of from 7 to 28 days, said second dosages each comprising carvedilol in an amount of about 12.5 mg, and then administering to said patient maintenance third dosages once or twice daily, said third dosages each comprising carvedilol in an amount of about 25.0 mg or about 50.0 mg.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Phyllis G. Spivack whose telephone number is 571-272-0585. The Examiner can normally be reached from 10:30 to 7 PM.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Ardin Marschel, can be reached 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

April 2, 2006

Phyllis Spivack

1614

Phyllis Spivack

PHYLLIS SPIVACK
PRIMARY EXAMINER